

Translation

PATENT COOPERATION TREATY

PCT/JP2003/013476



# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference D3-A0205P	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/013476	International filing date (day/month/year) 22 October 2003 (22.10.2003)	Priority date (day/month/year) 24 October 2002 (24.10.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/86, 5/10, 7/01		
Applicant DNAVEC RESEARCH INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) 1 disc, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
  - ☒ Box No. I Basis of the report
  - ☐ Box No. II Priority
  - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Box No. IV Lack of unity of invention
  - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Box No. VI Certain documents cited
  - ☐ Box No. VII Certain defects in the international application
  - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 23 April 2004 (23.04.2004)	Date of completion of this report 25 August 2004 (25.08.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/013476

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☐ in written format
    - ☒ in computer readable form
  - c. time of filing/furnishing
    - ☐ contained in the international application as filed
    - ☒ filed together with the international application in computer readable form
    - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
    - ☐ received by this Authority as an amendment\* on \_\_\_\_\_
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

*\* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/JP 03/13476**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-5	YES
	Claims	6, 7	NO
Inventive step (IS)	Claims	1-5	YES
	Claims	6, 7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

**2. Citations and explanations**

Document 1: Y. SAKAI et al., FEBS Letters, 1999, Vol. 456, pp. 221-226

Document 2: Y. IKEDA et al., Experimental Eye Research, July 2002, Vol. 75, No. 1, pp. 39-48

Document 3: A. SHIOTANI et al., Gene Therapy, 2001, Vol. 8, No. 14, pp. 1043-1050

Document 4: Y. YONEMITSU et al., Nature Biotechnology, 2000, Vol. 18, No. 9, pp. 970-973

**Claims 6 and 7**

Document 1 indicates the production of a Sendai virus vector (SeV) that comprises the EGFP gene, the transfection of the vector in question into a CV1 cell line from a simian kidney, and the confirmation of the expression of said gene.

The invention that is set forth in claim 6 of the present application is used in the transmission of genes to an activated T cell; however, in the light of the disclosures in the description, the configuration thereof does not differ from the vector that is disclosed in document 1 as a vector. In addition, although the virus vector that is set forth in the present application is only applied in the transmission of genes to an activated T cell, it is considered to be possible to employ said

configuration in the transmission of genes to other cells.

Thus, the invention that is set forth in claim 6 of the present application cannot be differentiated from the invention that is disclosed in document 1, and therefore it lacks novelty. The same is true in relation to claim 7 of the present application.

#### Claims 1-5

Document 2 indicates that a foreign gene (lac Z) has been introduced into a cell from retinal tissue by means of a Sendai virus vector.

Document 3 indicates that the Igf1 gene has been introduced into a cell from skeletal muscle tissue by means of a Sendai virus vector.

Document 4 indicates that a foreign gene has been introduced into a cell from respiratory epithelium tissue by means of a Sendai virus vector.

However, the feature of using the Sendai virus vector or another vector from a Paramyxovirus in order to introduce a foreign cell into an activated T cell is not disclosed or suggested in any of documents 1 to 4. Consequently, claims 1 to 5 of the present application are novel, involve an inventive step and are industrially applicable.